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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 475,704	12 30 1999	SUSAN W. BARNETT	1632,002	6738

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EXAMINER

WHITEMAN, BRIAN A

ARTICLE PAPER NUMBER

1638

DATE MAILED 02 26 2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/475,704	Applicant(s) BARNETT ET AL.	
	Examiner Brian Whiteman	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) 11-23, 41, 44-48, 61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 24-40, 42, 43, 49-60, 62-67 and 74-75 is/are rejected.
- 7) ☒ Claim(s) 68-73 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 01 December 1902 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>20</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Non-Final Rejection

Claims 1-75 are pending.

Applicants' traversal, the amendment to claims 1, 2, 37, 49, and 63, in paper no. 20 is acknowledged and considered.

Noncompliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

If the applicants do not comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures in the response to this office action, the response will be considered non-responsive.

Claims 11-23, 41, 44-48, 61 are still withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Information Disclosure Statement

Each U.S. Patent cited on the IDS in paper no. 19 was considered and initialed on the 1449 by the examiner. However, if the application was allowed the U.S. patents would not be printed on the patent. If the applicants want the US Patents to be printed should the application be in condition for allowance, the applicants should submit a 1449 listing the class/subclass for each US Patent listed on the 1449.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (pages 18, 26, 69). Applicant is required to delete any embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claim 1 is objected to because of the following informalities: misspelling of the word "immungenic".

Claims 67-75 are objected to because of the following informalities: the phrase "a polynucleotide of SEQ ID NO:" is in improper format. Suggest replacing with -- **the** polynucleotide of SEQ ID NO:--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 24-40, 42-43, 49-60, and 62-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 1-10, 24-40, 42-43, 49-60, and 62-66, as best understood, are readable on a genus of a polynucleotide sequence encoding a polypeptide including an immunogenic HIV Gag polypeptide, wherein the polynucleotide sequence encoding said Gag polypeptide comprises a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO: 1, 2, 3, or 4, wherein the genus of polynucleotide sequences is not claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification contemplates production of a genus of a polynucleotide sequence encoding a polypeptide including an immunogenic HIV Gag polypeptide, wherein the polynucleotide sequence encoding said Gag polypeptide comprises a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO: 1, 2, 3, or 4. The as-filed specification provides sufficient description of an immunogenic HIV Gag polypeptide set forth in SEQ ID NO: 3 or 4 and fragments of SEQ ID NO: 3 (SEQ ID NO: 1) and fragment of SEQ ID NO: 4 (SEQ ID NO: 2). Furthermore, the as-filed specification and art of record teach that Gag proteins of HIV are necessary for the assembly of virus-like particles HIV Gag proteins are involved in many stages of the life cycle of the virus including assembly, virion manufacture after particle release, and early post-entry step in virus replication. The role of HIV Gag proteins are numerous and complex (IDS, Freed, Virology, 1998). The specification contemplates that synthetic HIV Gag polypeptides can be measured for virus-like particle (VLP) production (page

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29). The claims recite a structure (polynucleotide encoding an immunogenic HIV Gag polypeptide), but do not recite a function for the genus of polynucleotide sequences. In addition, in view of the phrase "HIV Gag polypeptide", the polypeptide has to be identical to one found in an HIV in nature. The specification does not disclose how to distinguish between natural amino acid sequence and non-natural sequence that is also at least 90% identical. One skilled can envision a sequence that is at least 90% identical to the claims SEQ ID NOs., but would be unable to determine if it was an HIV sequence that was found in nature. Thus, in view of the reasons set forth above and the numerous and complex functions of HIV Gag polypeptides, the specification does not disclose which activities correspond to the claimed genus of polynucleotides with 90% sequence identity to the claimed SEQ ID NOs or how to distinguish between natural amino acid sequence and non-natural sequence that is also 90% identical.

However, it is apparent that on the basis of applicant's disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or molecular structures of molecules that are essential for the genus of polynucleotide sequences as claimed; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structures of polynucleotide sequences that must exhibit the disclosed biological functions as contemplated by the claims.

It is not sufficient to support the present claimed invention directed to a genus of a polynucleotide sequence encoding a polypeptide including an immunogenic HIV Gag polypeptide, wherein the polynucleotide sequence encoding said Gag polypeptide comprises a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID

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NO: 1, 2, 3, or 4. The claimed invention as a whole is not adequately described if the claims require essential or critical elements, which are not adequately described in the specification and which is not conventional in the art as of applicant's effective filing date. Claiming a genus of polynucleotide sequences that must possess the biological properties as contemplated by applicant's disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of a polynucleotide sequence encoding a polypeptide including an immunogenic HIV Gag polypeptide, wherein the polynucleotide sequence encoding said Gag polypeptide comprises a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO: 1, 2, 3, or 4 that must exhibit the contemplated biological functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Applicant's arguments filed 12/19/02 have been fully considered but they are not persuasive because they are not applicable to the new 112 written description rejection.

Claims 1-10, 24-40, 42-43, 49-60, and 62-66 remain and claims 74-75 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an expression cassette comprising the polynucleotide sequence set forth in SEQ ID NOs: 1, 2, 3, or 4 and a method of generating an immune response comprising administering to a subject a gene delivery vector comprising the expression cassette comprising the claimed polynucleotide sequence operably linked to a promoter, does not reasonably provide enablement for a polynucleotide sequence encoding a polypeptide including an immunogenic HIV Gag polypeptide, wherein the polynucleotide sequence encoding said Gag polypeptide comprises a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO: 1, 2, 3 or 4 and using any route of administration for generating an immune response in a subject using any type of composition (e.g. AAV, adenoviral, retroviral, etc.). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Specifically, since the claimed invention is not supported by a sufficient written description (for possession of a genus of a polynucleotide sequence encoding a polypeptide

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including an immunogenic HIV Gag polypeptide, wherein the polynucleotide sequence encoding said Gag polypeptide comprises a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO: 1, 2, 3 or 4, particularly in view of the reasons set forth above, one skilled in the art would not have known how to use and make the claimed invention so that it would operate as intended, e.g. used in an expression cassette for generating an immune response in a mammal.

The invention lies in the field of producing an immunogenic composition using an expression cassette comprising an HIV Gag polypeptide set forth in SEQ ID NOs: 1-4.

The specification contemplates: 1) Expression assays for the synthetic coding region of Gag and Gag-protease expression cassettes; 2) In vivo immunogenicity of Gag expression cassettes using plasmid DNA carrying the synthetic Gag expression cassette; 3) In vitro expression of recombinant alphavirus vectors or plasmid containing the synthetic Gag expression cassette; 4) In vivo immunogenicity of recombinant Sindbis replicon vectors containing Gag expression cassettes in mice by using intramuscular and subcutaneous routes.

The disclosure further claims that these experiments will exhibit increased potency for induction of cytotoxic T-lymphocytes (CTL) response and humoral immune response by using the Gag expression cassette.

The as-filed specification provides sufficient guidance for one skilled in the art to make an immunogenic composition comprising an expression cassette comprising of SEQ ID NO: 3 or 4 (and SEQ ID NO: 1 or 2) and for one skilled in the art to use a plasmid comprising the claimed cassette in a method of producing an immune response in a mammal by using i.m. administration of the plasmid.

However, the as-filed specification does not provide sufficient description or factual evidence for one skilled in the art to make and/or use a sequence having at least 90% identity to any of the sequences presented as SEQ ID NO: 1-4 other than the sequences themselves. The specification does not provide sufficient guidance for what amino acids of any of the sequences listed above may be changed while the Gag polypeptide activity is retained. In view of the state of the art describing the function of HIV-1 Gag proteins in the virus life cycle as exemplified by Freed, where Freed states that, "the role played by HIV-1 Gag proteins during the life cycle are numerous and complex, involving not assembly but also virion maturation after particle release and early post-entry steps in virus replication". Also, since the relationship of the sequence of a peptide and its tertiary structure (*e.g.* its activity) are not well understood and are not predictable (Ngo et al. The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), it would require an undue amount of experimentation for one skilled in the art in view of the prior art to arrive at other sequences that have at least 90% sequence identity to the Gag polypeptide encoded by SEQ ID NOs: 1-4 and still possess HIV Gag polypeptide activity.

Furthermore, with respect to claims 41-43, 49-60, 74 and 75 that encompass a composition or expression cassette for use in generating an immune response comprising a specific nucleotide sequence not operatively linked to a promoter. The specification provides sufficient guidance for one skilled in the art to make and use a gene delivery vector or composition comprising a polynucleotide operatively linked to a promoter. However, the

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specification fails to provide sufficient guidance or factual evidence for one skilled in the art to make and use an expression cassette or gene delivery vector, which expresses a nucleic acid sequence comprising a promoter that is not operatively linked to any specific nucleotide sequence in the claimed composition or expression cassette. The teachings in the specification are directed to using a promoter to express the polynucleotide sequence. The as-filed specification provides guidance or evidence for how to make and use vectors comprising a promoter operatively linked to a polynucleotide sequence to direct nucleotide expression, however the claims do not recite such a structural limitation. Thus, to the extent the claims fail to recite distinguishing features to commensurate with the level of guidance presented, the claims are not considered enabled.

In conclusion, the as-filed specification and claims coupled with the state of the art at the time the invention was made only provide sufficient guidance and/or evidence to reasonably enable making and using an expression cassette comprising the polynucleotide sequence set forth in SEQ ID NOs: 1-4, does not reasonably provide enablement for a polynucleotide sequence encoding a polypeptide including an immunogenic HIV Gag polypeptide, wherein the polynucleotide sequence encoding said Gag polypeptide comprises a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO: 1, 2, 3 or 4. One would have to engage in a large quantity of experimentation in order to practice the claimed invention based on the In Re Wands Factors including the lack of guidance in the application's disclosure, the unpredictability of producing nucleotide sequences encoding a HIV Gag polypeptide with 90% sequence identity to the claimed SEQ ID NOs. In addition, the prophetic examples as

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provided in the specification do not reasonably extrapolate to the full scope of the claimed invention.

Applicant's arguments filed 12/19/02 have been fully considered but they are not persuasive because they have not provided any new grounds to overcome the rejection set forth above. Thus, it is readily apparent that the as-filed specification fails to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute adequate enablement, e.g. Genetech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42, USPQ2d 1001, 1005 (Fed. Cir. 1997).

Furthermore, with respect to the assertion that skilled worker could have easily used the BLAST or any number of similar programs to determine the % identity as between sequences or could have readily generated any sequence falling within the scope of the claims using routine methods.

The court in Enzo 188 F.3d at 1374, 52 USPQ2d at 1138 states:

It is well settled that patent applications are not required to disclose every species encompassed by their claims, even in an unpredictable art. However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed.

In re Vaeck, 947 F.2d 48, 496 & n.23, 30 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991)(citation omitted). Here, however, the teachings set forth in the specification provide no more than a "plan" or "invitation" for those of skill in the art to experiment...; they do not provide sufficient guidance or specificity as to how to execute that plan. See Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993); In re Wright, 999 F.2d...[1557], 1562, 27 USPQ2d...[1510], 1514. [Footnote omitted].

On this record, it is apparent that the specification and the applicants' traversal

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(See page 7 of traversal, which states, "even if a rare construct were inoperable for some reason the skilled worker would have readily modified the construct according to the alternatives available at the time and described in the specification" provide no more than a plan or invitation in view of the art of record exemplifying the unpredictability of using making the claimed genus of polynucleotide sequences, for those skilled in the art to experiment with polynucleotide sequences having 90% identity to the SEQ ID NOs: 1-4 as intended by the as-filed specification at the time the invention was made.

See also Genetech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42, USPQ2d 1001, 1005 (Fed. Cir. 1997)

("Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable the public to understand and carry out the invention.")

In view of the art of record and the lack of guidance provided by the specification; the specification does not provide reasonable detail for what protocols are required for making and using a genus of the claimed polynucleotide sequences, and it would take one skilled in the art an undue amount of experimentation to reasonably extrapolate from the assertion in the specification to the full breadth of the claimed invention. Therefore, the as-filed specification is not enabled for the claimed invention.

Furthermore, the declaration under 37 CFR 1.132 filed 12/19/02 is insufficient to overcome the rejection of claims 1-10, 24-40, 42-43, 49-60, and 62-66 based upon 112 written description as set forth in the instant Office action because: Dr. Donnelly statements (See pages 5-7) indicate that a representative number of species of the claimed genus of polynucleotide sequences were not disclosed in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, to make and use a genus of claimed polynucleotide sequences without an undue amount of experimentation.

See in Enzo 188 F.3d at 1374, 52 USPQ2d at 1138 and Genetech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42, USPQ2d 1001, 1005 (Fed. Cir. 1997).

Double Patenting

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time-wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 6, 67, and 74-75 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 8, and 16 of co-pending Application No. 09/899,575. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of co-pending application '575 are drawn to an expression cassette comprising a polynucleotide comprising x contiguous nucleotides, wherein (i) the X contiguous nucleotides have at least 90% identity to Y contiguous nucleotides of SEQ ID NO: 51, 99, or 68 (claims 7, 8, 16, respectively). SEQ ID NO: 51 in claim 7 and SEQ ID NO: 99 in claim 8 are 100% identical to SEQ ID NO: 1 in the instant application. In addition, SEQ ID NO: 68 is 100% identical to SEQ ID NO: 2 of the instant application.

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Furthermore, claims 74 and 75 of the instant application '704 are obvious variants of claims 7, 8, and 16 of co-pending application '575 because the only difference between claims 74-75 of the instant application and claims of co-pending application '575 is using the expression cassette in a composition for producing an immune response in a mammal and a method of using the composition. One of ordinary skill in the art would have concluded that the invention defined in the claims in the application '704 is an obvious variant of the invention defined in the claims of the co-pending application '575.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 12/19/02 have been fully considered but they are not persuasive. Applicants have not provided a terminal disclaimer to overcome the double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635

Scott D. White
SCOTT D. WHITE, M.D.
PATENT EXAMINER